

REMARKS/ARGUMENTS

In view of the following remarks, favorable reconsideration of the pending claims is respectfully requested.

Claims 6 – 9, 11, 13 – 20, and 31 – 47 are currently pending. Claims 1 – 5, 10, 12, and 21 – 30 have been cancelled.

Claims 6 – 9, 11, 13 – 20, and 31 – 47 have been rejected 35 U.S.C. § 103(a) as being unpatentable over the combination of U.S. Patent No. 4,820,524 to Berta and U.S. Patent No. 6,406,738 to Hogan et al. Applicant respectfully traverses these rejections.

The Office Action alleges that Berta teaches a capsule-like medicant having a solid core that is coated with a multi-colored gelatin single coating layer, and therefore describes the claimed solid preparation. The Office Action further alleges that although the multi-colored tablet is prepared differently than the claimed tablet, it is the product that must be patentable and not the process by which it is made.

The Office Action also cites Hogan for allegedly teaching a method of applying radiation to a powder coating material to provide a medicant (i.e., tablet) having a multi-colored continuous coating, and therefore it would be obvious to treat the multi-colored tablet of Berta with radiation as taught in Hogan to arrive at the claimed invention.

The Office has failed to make a *prima facie* case of obviousness because 1) the combination of references fails to teach each and every claim element and 2) because there is no motivation to combine the references. Specifically, the combination of references fails to teach a solid preparation having a continuous multi-colored film coating layer. Additionally, the combination of the references fail to disclose or suggest the steps that are necessary to arrive at the claimed invention and therefore fail to disclose or suggest the claimed structure that is arrived at with the claimed method steps.

1. **The Combination of Berta and Hogan Does Not Disclose or Suggest Each and Every Element of Independent Claims 31 and 33.**

Applicants respectfully submit that the combination of Berta and Hogan fails to disclose or suggest the claimed invention. Specifically, the combination of the cited references fails to disclose or suggest a solid preparation having a multi-colored continuous film coating layer.

The combination of the references fails to disclose or suggest a solid preparation having a multi-colored continuous coating. Berta teaches a tablet having a multi-colored coating that is obtained by individually dipping and drawing first one end and then the other end of each tablet into a bath of gelatinous coating. See Abstract. In particular, Berta describes that an exposed end is dipped into the bath and then dried. After drying, the uncoated end is dipped into a second bath and then dried to provide a multi-colored coating. See column 5, lines 48 – 65. From this excerpt, it can be seen that the coating described in Berta is not a single continuous coating, but rather comprises two separate coating layers that are separately applied to the tablet. Thus, Berta does not disclose or suggest a solid preparation having a multi-colored continuous film coating layer as recited in independent Claims 31 and 33.

Hogan also fails to disclose or suggest a solid preparation having a multi-colored continuous film coating layer. Hogan describes a process for preparing a multi-colored tablet in which a first coating powder is electrostatically applied to one portion of the tablet followed by exposing the coating to electromagnetic radiation, such as infrared radiation, to cause the powder to melt and form a liquid. See column 4, lines 32 – 44. Upon cooling, the liquid forms a coating on the surface of the tablet to which it has been applied. In a subsequent step, a second coating powder of a different colorant is electrostatically applied to the uncoated portions of the tablet, followed by exposure to electromagnetic radiation as described previously to form a multi-colored tablet. From this discussion, it can be seen that the multi-colored coating of Hogan also comprises two distinct coatings and does not have the presently claimed multi-colored continuous coating layer.

In contrast to the cited references, independent Claims 31 and 33 recite a solid composition having a multicolored continuous film coating layer. As noted above, both Berta and Hogan describe tablets/tablets having two separate coatings that are separately applied to the

solid preparation. Accordingly, Berta and Hogan do not disclose or suggest the claimed invention when considered singly or in combination.

Further, the combination of references fails to disclose or suggest the step of selectively irradiating the continuous coating to produce a coating having two distinct colors. This step is neither suggested nor disclosed by the cited references. In fact and as discussed in greater detail below, there is no teaching in either of the references that irradiating the coating would produce any sort of color change in the coatings. As such, the combination of the references fails to disclose or suggest the steps that are necessary to arrive at the claimed invention and therefore fail to disclose or suggest the claimed structure that is arrived at with the claimed method steps. That is, the cited references fail to disclose or suggest a process that can be used to prepare a solid composition having a multicolored continuous film coating layer.

2. One of Ordinary Skill in the Art would not be motivated to combine Berta and Hogan as contemplated by the Examiner.

The Office Action asserts that it would be obvious to one of ordinary skill in the art to incorporate the powder coating material methods of Hogan, which comprise the step of applying radiation, within the multi-colored tablets of Berta. The Applicants respectfully disagree with this assertion for several reasons.

First, one of ordinary skill in the art would not be motivated to irradiate the tablet of Berta because to do so would serve absolutely no purpose. As discussed above, Berta describes a process of preparing a multi-colored tablet in which a multi-colored coating is obtained by individually dipping and drawing first one end and then the other end of each tablet into a bath of gelatinous coating. Each end is dipped into its respective bath and then dried. Berta describes that each bath includes a different colorant so that the resulting tablet has two coatings of different coloring. In contrast, the process of Hogan describes a process in which electrostatically charged particles are irradiated to melt the particles together to form a coating. The thus formed liquid coating is allowed to cool to form a solid coating. Accordingly, the irradiation step in Hogan is necessary in order to melt and fuse the particles together in order to form a coating. Such a step is unnecessary in the process of Berta and would in fact serve no

purpose because the coating of Berta is provided as a liquid and as such there is no reason to apply irradiation to fuse the coating together as in Hogan. In fact, such a step would be counter productive because it would prevent or hinder the drying of the gelatinous coating. It cannot be predicted what would happen if the coatings of Berta were exposed to the irradiation step of Hogan. It is probable that such a step would result in melting the coating of Berta. Accordingly, one of ordinary skill in the art would not modify the process of Berta to include the step of irradiating the coating as taught in Hogan.

Second, both Hogan and Berta teach using separate coating materials of different color to form a multi-colored coated tablet. For instance, Berta teaches dipping a first exposed portion of the tablet into a bath of a first color, followed by dipping a second exposed portion of the tablet into a second bath of a different color to obtain a multi-colored tablet in which the two portions of the tablet are of different colors. Having thus obtained the multi-colored tablet, one of ordinary skill in the art would not be motivated to then expose selective regions of the tablet to irradiation to obtain a further color change. Such a step would serve absolutely no purpose since the tablet of Berta has previously obtained the desired multi-colored appearance. As such, one of ordinary skill in the art would not be motivated to irradiate the tablets of Berta.

Finally, neither Berta nor Hogan include any teachings that their respective coatings would change color upon being irradiation. There is absolutely no basis for suggesting that the irradiation step of Hogan would result in changing the color of the coatings of either Berta or Hogan. In fact, the only possible suggestion for such a step comes from Applicants' own teachings. It is clear that the Office Action is using Applicants' own teachings in making this rejection. This is impermissible use of hindsight. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). For this additional reason, one of ordinary skill in the art would not be motivated to modify the process of Berta to include the step of irradiating the coatings as taught in Hogan.

The Office Action also asserts that Hogan teaches applying radiation, such as ultraviolet light, to the tablet. However, this teaching is directed to curing the coating to form a cross-linked polymer film. There is absolutely no teaching in Hogan of using radiation to selectively effect a

color change in the tablet coating, or as noted above, that the coatings of Berta or Hogan would even be susceptible to changing color by being exposed to radiation, such as ultraviolet light.

3. The combination of Berta and Hogan does not provide predictable results.

In *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (U.S. 2007), the Supreme Court held that in determining obviousness, one must look to whether the combination of the elements provides a predictable result. In the present case, one of ordinary skill in the art would not be motivated to use the irradiating step of Hogan in the process of Berta because the result would be unpredicable.

As noted above, there are absolutely no teachings in the cited references that the irradiation would effect a color change in any one of the coatings of Berta or Hogan. As such, the irradiation step of Hogan cannot be applied to the tablet of Berta in a predictable manner because there is no teaching on how such a step would affect the coatings of Berta.

Further, it cannot be predicted how irradiation would affect the structure of the coatings of Berta. As discussed above, the irradiation step of Hogan is provided to melt the individuals particles of Hogan so that upon cooling they are able to fuse together to form a coating. However, the coatings of Berta are applied as a liquid gelatinous coating that is then dried. In other words, there is no need to melt the coating because it is already a liquid. As such, applying the irradiation step to the coating of Berta may cause the individuals coatings to melt, which can result in portions of the melted coatings running together or dripping off the tablet. This would cause the tablet losing uniformity in the coating, which would result in the tablet having an unsightly appearance. As such, using the irradiating step of Hogan in the process of Berta would result in the tablet being unsatisfactory for its intended purpose. This is a clear indication that a lack of predictability exists in arriving at the claimed invention based on the combination of Berta and Hogan.

In view of the foregoing remarks, it can be seen that the claimed invention is patentable over the cited references because Berta and Hogan, whether considered individually or in combination, fail to disclose or suggest a solid composition having a multicolored continuous

film coating layer. Further, one of ordinary skill in the art would not be motivated to modify Berta to include the irradiation step of Hogan as contemplated by the Office.

4. The combination of Berta and Hogan does not teach a continuous multi-colored coating layer in which the coating layer includes logos, bar codes or letters as part of the coating.

With respect to dependent Claims 18 – 20 and 44 – 47, there is absolutely no teachings in either Berta or Hogan on how their respective teachings can be modified to produce a coating having a pattern, logo, bar code or letters. The Office Action completely fails to disclose how such a coating could be obtained by modifying the cited references. The Office Action glosses over this glaring deficiency by stating that the inclusion of logos, bar codes or letters as instantly claimed does not make the invention patentable since variations in designs or patterns in solid medicament forms is commonly and routinely practice in the pharmaceutical art. This statement completely fails to address or cite any prior art that teaches a solid preparation having a continuous multi-colored coating layer in which the coating layer includes logos, bar codes or letters as part of the coating. This element is completely missing from the cited art. The fact that it is known to include caplets/tablets with logos, bar codes, or letters does not disclose or suggest a continuous coating layer having such as part of the coating. If the Office intends to maintain this rejection, it is respectfully requested that the Office specifically articulate where such a teaching can be found in the cited art.

Furthermore, the tablet of Berta is dipped into two different baths to produce a multi-colored tablet. There is absolutely no teaching of how such a method could be used to produce a continuous coating with a pattern, such as a logo, bar code or letters in which the pattern is part of the coating. Accordingly, there is absolutely no teachings in either Berta or Hogan of a solid preparation having a continuous multi-colored coating layer in which the coating layer includes logos, bar codes or letters as part of the coating.

In view of the foregoing remarks, it is respectfully submitted that the rejections under 35 U.S.C. § 103(a) have been overcome, and that the pending claims are in immediate condition for allowance.

Appl. No.: 09/842,466
Amdt. dated 01/15/2008
Reply to Office Action of 09/10/2007

Conclusion

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Timothy J. Balts', with a long horizontal stroke extending to the right.

Timothy J. Balts
Registration No. 51,429

Customer No. 00826
ALSTON & BIRD LLP
Bank of America Plaza
101 South Tryon Street, Suite 4000
Charlotte, NC 28280-4000
Tel Charlotte Office (704) 444-1000
Fax Charlotte Office (704) 444-1111
LEGAL01/13061267v1

ELECTRONICALLY FILED USING THE EFS-WEB ELECTRONIC FILING SYSTEM OF THE UNITED STATES PATENT & TRADEMARK OFFICE ON January 15, 2008.